Instructions for the submission of a study/research proposal to be reviewed by the Ethical Review Committee for Research in Human Subjects, Ministry of Public Health

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In order to expedite and facilitate the review process of a research proposal, an applicant should follow these instructions:

1. The principle and methodology of a submitted proposal should comply with the criteria set by the Ethical Review Committee.

2. For a research proposal on AIDS vaccine, in addition to the compliance with the criteria mentioned in item 1, it has also to be in line with the criteria for the study on AIDS vaccine identified by the Committee.

3. A submitted proposal should comprise topics as described in the Guidelines for the preparation of a research proposal.

4. Twenty-one Protocol (original 1 and copies 20) of the research proposal (for the study on AIDS vaccine, 24 protocol (original 1 and copies 23) are required) should be submitted to:

The Office of the Secretary,
Ethical Review Committee for Research in Human Subjects,
Department of Medical Services,
3th floor of the Building No.2, Ministry of Public Health
Tiwanond Road, Nonthaburi 11000
Tel. 02-5918251, 02-590-6171-2
Fax. ,02-5918251
E-mail porntiva@health.moph.go.th หรือ prntvc@yahoo.com

5. The review process:

5.1 The submitted research proposal will be initially reviewed by at least two advisers. For AIDS vaccine study, at least three advisors are required.

5.2 The proposal will be finally reviewed by the Ethical Review Committee at its regular meeting. The following procedures are routinely carried out in the meeting:

a) The advisors will present to the Committee the summary of the proposal with detailed ethical considerations and other relevant comments.

b) The Committee members will discuss and make a list of inquiries to be clarified by the principle investigator.

c) The Principle Investigator or his/her representative will be invited to give explanation and answer the questions inquired by the Committee. He/she will be requested to;

- introduce himself/herself
- brief about the research proposal
- answer the questions

d) By principle, the Committee will review both on ethical and scientific aspects of the research proposal.

e) At the conclusion, Principle Investigator or his/her representative will be informed of the initial result. The official result will be notified to the researcher in due course.

6. The Committee's considerations will be concluded in one of the following alternatives:

6.1 The research proposal is approved. (without any condition)

6.2 The research proposal is approved with some conditions, i.e. with some recommendations for the proposal revision.

6.3 The consideration has been pending or the research proposal has not been taken into consideration.

6.4 The research is not approved.

7. The result of the Committee's consideration will be reported to the Chairman and the Permanent Secretary for Public Health respectively. A letter of notification signed by the Permanent Secretary for Public Health will be forwarded to

7.1 The Principle Investigator

7.2 The responsible organization.

This process will take about 2-3 weeks. However, the overall review process will take approximately 2-3 months (from the receiving date of the proposal until the final decision is made and notified to the persons concerned.)

8. Implementation

8.1 If the submitted proposal is approved without any condition, the research can be conducted at once.

8.2 In case the proposal is approved with some conditions, it has to be revised as recommended by the Committee and sent back to the secretary for further actions:

a) For the revised proposal with a slight modification, it will be checked by the secretary, if agreeable, the researcher will be informed to carry out the study.

b) In case modification is made on the main part of the proposal, the secretary will forward the revised copy to the advisor for comments and then submits further to the Ethical Review Committee for consideration. The researcher might be invited to give additional explanation, if needed. After the proposal is approved, the researcher will be notified of the result.

8.3 The research proposal which is pending, and has not been taken into consideration by the Committee, must be those that need to be totally revised and re-submitted.

9. As soon as the researcher is verbally informed of Committee's approval of the proposed study, a copy of the letter of approval will be made available to the researcher, if needed, for further action and also to enable him/her to process a request for the importation of essential products to be used in the research work.

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Guidelines for the preparation of a research proposal submitted to the Ethical Review Committee for Research on Human Subjects, Ministry of Public Health

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The Thai protocol (original 1 set and 20 copies) is combined with details as follow (English protocol can attach for review)

1. Title of the project

Title of the project must be stated precisely in Thai language. If an English title is supplemented, the meaning of both languages should be exactly the same.

2. Name and address of the principal investigator(s) and the institution(s).

3. Project Summary (not to exceed 2 pages).

The full protocol should include the topics 4-14:

4. Introduction

The introductory section should include:

4.1 Background information

4.2 Justification

4.3 Expected benefits from the proposed study

5. Objectives

6. Location and duration of the study

7. Work plans

The work plan to outline the following activities and information:

7.1 Population participating in the study (both the experimental and the control groups) with the details of sex, age, other characteristics, disease or specific symptoms, and number of subjects.

7.2 Inclusion criteria

7.3 Exclusion criteria

7.4 Discontinuation criteria which include:

a) Discontinuation criteria for participants.

b) Criteria for termination of the study.

7.5 Implementation and monitoring procedures, including data collection and analysis.

7.6 Special considerations

a) If blood examination is required objective, number, quality and frequency of blood collections must be specified.

b) In case of clinical trial of a drug, the trade name and the generic name of the drug, manufacturer's and distributor's names including the registration number of drug license are required.

c) In case of using other non-pharmaceutical products, documents of detailed information on the products and the results of relevant research must be attached.

d) For research/study that requires an operation or any medical practice, the method of work must be described.

8. Ethical considerations

The following issues and documents should be prepared:

8.1 Possible risks including preventive or alleviative measures

8.2 Compensation, medical care and other services to be provided to the subjects who many be affected by any complication.

8.3 Other related ethical aspects

8.4 Human subject information sheet in Thai language, in which physician or hospital's name, contact address and telephone number have been included. The information sheet should follow the model attached.

8.5 Consent of volunteers should be submitted on the form already approved by the Committee. Other similar forms can be an alternative.

8.6 In case the researcher considers that there is no need for the information sheet or the consent form, the researcher must propose the rationale for approval from the Committee.

9. Detail Budget and Source of Funding.

10. References.

11. Curriculum vitae of all researchers (may be submitted on a separated sheet)

12. Letter of approval from the implementing institution.

13. Result of ethical or human right review by an ethical committee of the studying institution (if available)

14. The research proposal has to be signed by the principal investigator(s) or project team leader and all participating researchers.

15. Total Questionnaire/ data collection in research

16. The letter signed by a principle investigator's supervisor.

17. For the international project, Thai and foreign Principal investigator in each side is required

18. The Ethical Review Committee for Research in Human Subjects, Thai Ministry of Public Health had reviewed both Thai and English protocols. In ethical concern, the committees has reviewed and approved for implementation of the research study mention above, therefore the Thai protocol will be mainly conduct.

19. Material transfer agreement need for transfer blood or biomedical sample

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Estimated Expenditure per year

Project Title : ……..
……
Principal Investigator :
……
……
Responsible Organization :
……
……
Source of Funding :
……
……
……
Duration : per year
……

Budget Justification :

1. Salary :
   ……
   1.1 full time staff …….. duration …… month (s)
   …….. Baht (s)
   1.2 part time staff …….. duration …… month (s)
   …….. ……..Baht (s)
2. Honorarium for researchers :
   …….
3. Honorarium for consultants :
   ……
4. Subsidy for participants :
   ……
5. Curative cost (if any) :
   ……
6. Operation cost :
   ……
7. Report printing :
   ……
8. Others :
   ……

Total …….. Baht (s)

Information Sheet

Instruction

1. The information sheet should provide essential information for prospective research subjects. The information should be complete, concise and in language that he or she is capable of understanding.

In case a volunteer is the minority who cannot read Thai language. Translation to their language is required. Thai version must be used as the original for translation and a translated document must be submitted in the same time as submit the protocol in the beginning. The translator who registers at the court or Ministry of Foreign Affairs may be obtained.

2. For the sake of completeness and easy to read, the information sheet should be written in structured form.

3. The information sheet and informed consent certificate can be combined or separated. In case of a combined form, the consent certificate should be clearly separated in the latter part.

4. The information sheet and a copy of consent certificate should be kept by each participants. The investigator should hold the signed consent certificate.

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Note : Please follow Thai version

Information Sheet

1. Title of Protocol
2. Name and title of principle investigator
3. Office:
   Address
   Telephone No.
   - Office
   - Home
   - Mobile

   Fax.
   Pager
4. Essential Information's include :
   4.1 Rationale for research.
   4.2 Purpose of research.
   4.3 Methods of the research.
   4.4 The expected duration of the subject's participation.
   4.5 The benefits that might reasonably be expected to result to subject or to others as an outcome of the research; when there is no direct benefits to the subject, the subject should be made aware of this.
   4.6 Any foreseeable risks or discomfort to the subject, associated with participation in the research, both physical and psychosocial risks.
   4.7 Prevention of anticipated risks and measures prepared to cope with problem.
   4.8 Any standard or alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being test.
   4.9 The extent to which confidentiality of records in which the subject is identified will be maintained.
   4.10 The extent of the investigator's responsibility, if any, to provide medical services to the subjects.
   4.11 The therapy to be provided free of charge for specified type of research related injury.
   4.12 The anticipate prorated payment, if any, to the subject.
   4.13 Whether the subject or subject's family or dependants will be compensated for disability or death resulting from such injury.
   4.14 That the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.
   4.15 Name, address, telephone numbers of physicians or other research team to be contacted conveniently 24 hrs. both during on or out of duty in case of need or emergency.

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Ethical Criteria
The Ethical Review Committee for Research in Human Subjects
Ministry of Public Health, Thailand
1993 (Revised 1995)

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1. The Ministry of Public Health (MOPH) is responsible for reviewing ethical issues in the medical research which meet the following criteria :
   (1) Conducted by the MOPH's personnel or organizations, or conducted in geographical areas under responsibility of the MOPH.
   (2) Requested by other organization for ethical review.
   (3) Requiring national authority approval.

2. The submitted proposals should
   (1) be based on Thai legislation, notification and merit consideration ;
   (2) be conducted by Thai investigator(s) or at least 1 Thai investigator in the team;
   (3) have at least one competent medical officer to treat any effect incurred upon the subject's physical or mental health as the result of the study ;
   (4) state specific and achievable objective (s) ;
   (5) justified the needs to do the study on human subject ;
   (6) lead to new and useful findings and knowledge ;
   (7) be restricted to the minimum number of subjects as determined by statistical techniques ;
   (8) be translated into Thai (for proposal originally in foreign language) ;
   (9) transmit 3 copies, both Thai and English, of Final Report to the Ethics Committee within 6 months after project completion.

3. Research involving human subject must have adequate and qualified evidences to substantiate its safety based on animal experiments or previous knowledge.

4. The subject or his/her legal guardians must have agree to the study by signing the consent form after being properly informed. The consent from should follow the MOPH requirement.

5. Research activities must be conducted by qualified and experienced investigator(s) who understand the research process, benefits and potential harmful effects. Command facilities required for the safe and efficient treatment of the subject when needed.

6. Principal Investigator(s) have to explain clearly to potential subjects, as follows :
   (1) plan and method of studies ;
   (2) potential hazards or discomfort that may occur and preventive measures ;
   (3) benefit to themselves and to the country ;
   (4) their rights and freedom to withdraw from the studies ;
   (5) any other information as required by potential subjects to ensure full agreement and avoid misunderstanding from the potential subjects.

7. Principal Investigator(s) should select methods of study which will cause minimal impact on the subject's physical and mental health.

8. Each activity involving human subjects must be conducted under caution based on medical standard. Any methods found to indicate potential hazards to the subjects must be ceased immediately.

9. Principal Investigator(s) must report to the Committee or the Monitor/DSMB in case of serious adverse reaction as determined in the Guidelines for Good Clinical Practice [GCP].

10. Subjects or their legal guardians are free to withdraw the consent to participate in the study. The withdrawal will not affect any entitlement to those treatment that may be required under normal circumstances.

11. The Ethics Committee has the right to set any future guidance or regulation as deem necessary.

Ethical Considerations for conduct of AIDS Vaccine Trials/Studies in Thailand The Ethical Review Committee for Research in Human Subjects Ministry of Public Health, Thailand 1993

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The Ethical Review Committee for Research in Human Subjects Ministry of Public Health, Thailand has realized the necessity of promoting research on AIDS vaccines. The Committee has developed guidelines for AIDS vaccine studies which will serve to :

1) Increase understanding by Principal Investigator(s)/institutions involved with regards to the ethical assessment of research proposals.
2) Facilitate the review process.
3) Ensure protection of volunteers/subjects in terms of health, human rights and compensation.

The details of criteria are as follows :

1. A submitted proposal shall be attached with documented evidences showing the following :
   (1) Approval for studies in Phase I, Phase II or Phase III issued by the national authorities dealing with vaccine trials and development in the country of origin such as Investigational New Drug (IND), Food and Drug Administration (FDA), or National Institutes of Health (NIH).
   (2) Certificate of Good Manufacturing Practice (GMP).
   (3) Approval and agreement for the studies issues by the institution where the Principal Investigator(s) are working and other collaborating institutions.
   (4) Detailed list of budget and itemized expenditure as well as sources of funds using the attached form.
   (5) Measures to safeguard the following ethical aspects ;
      - confidentiality concerning personal information on volunteers/subjects;
      - methods of data collection, processing and dissemination ;
      - researcher's responsibility to volunteers/subjects ensuring adequate medical treatment and care resulting from adverse effects or reactions which, in some cases, may be fatal; and preventive measures against such events and also protection form social discrimination ;
      - provision of appropriate compensation to be given to the volunteers/subjects or to his or her heirs in the event of harmful effects;
      - provision of regular counseling services and health education to avoid risk behavior ;
      - informing the subjects of his or her rights and freedom to withdraw from the project at any time.
   (6) Clear statement of the benefits of the study to the investigators, institutions and the nation.
   (7) Submission of a sample consent form.

2. The existing ethical criteria currently used to assess proposals for biomedical research in human subjects will also be applied to deliberate AIDS vaccine proposals.

3. The Committee will meet at every twice time/months to consider all proposals. The result of the Committee's deliberation will be reported to the Principal Investigator(s)/institutions within 3 months after initial consideration.

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Additional Suggestion of the committee

1. Incase of residual blood sample from the study (not the intentional extra-drawn blood) and the additional blood drawn for further study, the below requirements must be followed:
   Definition: Blood means blood and component of blood such as DNA, serum, protein marker etc.
   - Duration of blood sample storing must be clarified
   - Specimen storage must be in Thailand
   - Approval from the committee must be obtained prior to utilizing of these blood samples.
   - Project plan, which related to the previous study, must be identified.
   - Approval from the storage's owner must be obtained.
   - Applying for commercial benefits is prohibited.
   - Benefits to volunteers or communities must be clarified.
   - Utilizing is limited only to the previous-related projects, no genetic study is allowed.

2. Subject's information must be used in compatible projects, within the exact time frame, and with emphasizing on subjects' right.

3. Serious adverse events must be reported within 10 days after acknowledgement of these events. The investigations should analyze how these adverse events relate, possible/likely, probably related, fatal to their responsible project. In addition, regulations to protect subjects in Thailand must be identified.

4. Copies of approval document from The Ethical Review Committee as well as agreement document form cooperative institutes must be submitted. Submission can be delayed if they are not ready yet.

5. Investigators must prepare assent form for subjects age over 12 years and have yet completed 20 years.

6. In case of over 5 pages information document, maximum 3 pages of summary information sheet must be provided.

7. At least 2 witnesses, who have not involved with the study must sing in the consent form.

8. Report of Project status must be performed yearly.

9. In case of extension of the project, report of implementation and request for extension must be submitted before the study ended.

10. When the study ended, either complete or unable to continue the study, the committee must be informed with the explanation.

11. Any change in the project must be clarified with what, how and why the change is.

12. Any change or addition of principal investigators or investigators, resume of the new persons together with the reason of change must be submitted to the committee.

13. Revision of the project according to the committee' s suggestion must be done within 1 year since the submission date. Otherwise it implied that you want to cancel the project. Then, reviewing form the first step must be carried out if the project is submitted again.

14. In case of sending study specimens for testing abroad, material transfer agreement (MTA) form must be submitted

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Sample of MTA